DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1339]

Pilot Program for Request for Designation and Pre-Request for Designation Electronic Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office of Combination Products (OCP) in the Food and Drug Administration (FDA) is soliciting applications from members of the public interested in participating in a voluntary pilot program to help OCP evaluate a potential new electronic submissions process for Requests for Designation (RFD) and Pre-RFD. This RFD and Pre-RFD electronic submission process is intended to improve efficiency and completeness of RFD and Pre-RFD submissions. OCP plans to accept up to nine participants for the pilot program. The pilot program is intended to provide OCP input to inform this evaluation.

DATES: Interested parties should submit an electronic application to participate in this pilot program by August 19, 2020. We plan to conduct pilot testing beginning on or about August 26, 2020. See section III of this document for information on applying for participation.

FOR FURTHER INFORMATION CONTACT: Danita Dixon, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2889, *danita.dixon@fda.hhs.gov.*

ADDRESSES: If you are interested in participating in this pilot program, please submit an electronic application to *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their products. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biological product, or a combination product, and which medical product FDA Center (Center for Devices and Radiological Health, Center for Drug Evaluation and Research, or Center for Biologics Evaluation and Research) will regulate it if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see ''How to Write a Request for Designation (RFD)'' at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd*). A second option referred to as the Pre-RFD submission process, is for a sponsor to submit an inquiry to OCP to receive a preliminary assessment of their product's classification and/or assignment, which is not binding. The Pre-RFD process allows for more flexible interaction between sponsors and FDA. RFD and Pre-RFD submissions to OCP are currently, typically submitted via email, although some are submitted in paper copies. Regardless of format, some submissions lack sufficient data for review. Consequently, OCP is announcing a pilot program to test the functionality of a more structured RFD and Pre-RFD electronic submission process that should enhance efficiency and ensure sponsors' understanding of required and recommended submission content.

II. Pilot Program Participation

The pilot program to evaluate the RFD and Pre-RFD electronic submission processes is to last approximately 2 weeks. During the pilot program, OCP staff will be available to address questions or concerns that may arise. Pilot program participants will receive training and will be asked to submit simulated regulatory submissions using data provided to them by OCP for testing purposes. Pilot program participants will also be asked to provide written and verbal feedback during their training and after they submit the simulated regulatory submissions. This feedback will assist OCP in developing the electronic submission processes. OCP estimates that each individual participant's involvement may require about 15 hours over the 2-week period. OCP is soliciting applications from members of the public, such as combination product and other medical product sponsors, as well as entities that may act as authorized agents submitting RFDs or Pre-RFDs for sponsors. At its discretion, OCP may withdraw a participant from the pilot program for not completing the requested activities within requested timeframes.

III. Applications for Participation

Send applications to participate in the pilot program to *combination@fda.gov.* Applications should include the following information: Company and contact name, contact phone number, and contact email address. Additionally, although not required for consideration, OCP is particularly interested in whether you are a sponsor or may act as an authorized agent, and whether you have previously submitted an RFD or Pre-RFD. Once applications for participation are received, FDA will contact interested applicants to confirm selection for the pilot program. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot program.

Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17039 Filed 8–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 4, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information

collection is 0910–0834. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Information Sharing Among Constituent Part Applicants for Combination Products—21 CFR 4.103

OMB Control Number 0910–0834—Extension

This information collection request applies to ''constituent part applicants'' as defined under 21 CFR 4.101 (*i.e.,* any person holding an application under which a constituent part (drug, device, or biological product) of a combination product received marketing authorization if the other constituent part(s) received marketing authorization under an application held by a different person). Under this collection, constituent part applicants must share safety information they receive related to certain events with the other constituent part applicant(s) and maintain associated records.[1]

In the **Federal Register** of April 30, 2020 (85 FR 23971), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE AND RECORDKEEPING BURDEN

21 CFR section; activity	Number of respondents/ recordkeepers	Number of disclosures/ records per respondent/ recordkeeper	Total annual disclosures/ records	Average burden per disclosure/recordkeeping	Total hours
4.103, Sharing information with other constituent part applicants.	33	18	594	0.35 (21 minutes)	208
4.103(b) and 4.105(a)(2), Records of information shared by constituent part applicants.	33	18	594	0.1 (6 minutes)	59
Total	.....	.....	.....	.....	267

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We note in this regard that FDA extended the compliance date for 21 CFR part 4, subpart B, until July 2020 for most combination products, and until January 2021 for the remainder, in response to stakeholder feedback, to ensure that Combination Product Applicants have sufficient time to update reporting and recordkeeping systems and procedures.[2] Consequently, entities subject to this rule have not yet had to comply with this information request.

Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17041 Filed 8–4–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-term) Multi-Disciplinary Working Group.

The meeting will be open to the public as indicated below via NIH Videocast. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The program documents and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group Meeting.

Date: August 31, 2020.

Open: August 31, 2020, 9:00 a.m. to 1:00 p.m.

Closed: August 31, 2020, 1:00 p.m. to 2:50 p.m.

Open: August 31, 2020, 2:50 p.m. to 4:30 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiative projects and obtain expertise from MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: The open portion of the meeting will be live webcast at: *https://videocast.nih.gov/.*

Place: National Institutes of Health Building 1, Wilson Hall, 1 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca G. Baker, Ph.D., Office of the Director, National Institutes of

[1] The Postmarketing Safety Reporting (PMSR) information collections for drugs, biological products, and devices found in §§ 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20 (21 CFR 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20) have already been approved and are in effect or their extension is being sought separately as required, including with respect to burden for combination products (reflected in the authorization for OMB control number 0910–0834, but, therefore, not addressed in this extension request). The pertinent PMSR information collection provisions for § 314.80(c) and (e), as well as for § 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for §§ 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for § 606.170 are approved under OMB control number 0910–0116. Those for § 606.171 are approved under OMB control number 0910–0458. The information collection provisions for §§ 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for §§ 806.10 and 806.20 are approved under OMB control number 0910–0359.

[2] See Compliance Policy for Combination Product Postmarketing Safety Reporting (April 2019) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting*).